

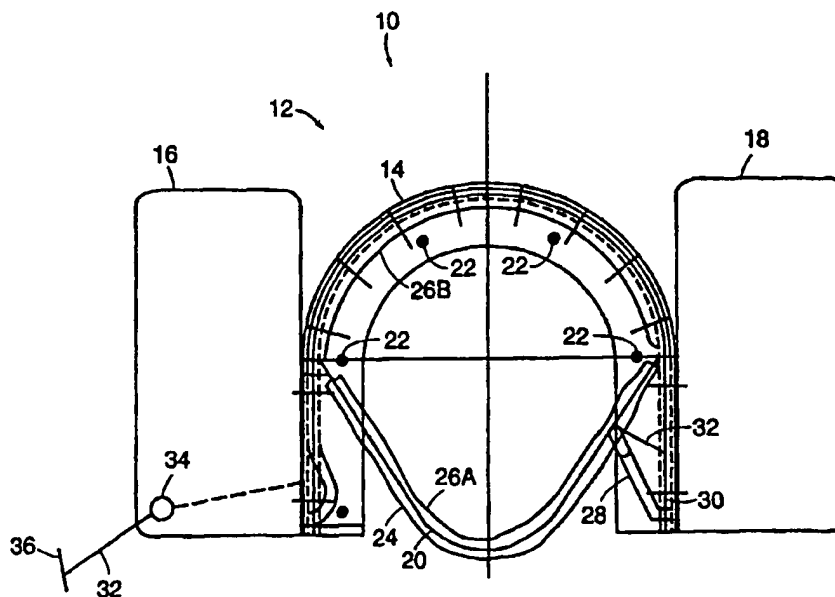
PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61B 10/00, A47K 11/10	A1	(11) International Publication Number: <b>WO 00/66005</b> (43) International Publication Date: 9 November 2000 (09.11.00)
(21) International Application Number: PCT/US00/11297 (22) International Filing Date: 26 April 2000 (26.04.00) (30) Priority Data: 09/303,988 3 May 1999 (03.05.99) US (71) Applicant: EXACT LABORATORIES, INC. [US/US]; 63 Great Road, Maynard, MA 01754 (US). (72) Inventors: SLOAN, Walker, M., III; 44 Coburn Road, Berlin, MA 01503 (US). LAPIDUS, Stanley, N.; 12 Old Evergreen Road, Bedford, NH 03110 (US). (74) Agent: SULLIVAN, Joseph, P.; Testa, Hurwitz & Thibault, LLP, High Street Tower, 125 High Street, Boston, MA 02110 (US).	(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  Published With international search report.	

(54) Title: STOOL SPECIMEN COLLECTOR



## (57) Abstract

The invention provides an apparatus for obtaining a stool specimen. The apparatus comprises a housing, a collection bag, a slider to close the collection bag and a draw string to move the slider.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

## STOOL SPECIMEN COLLECTOR

Technical Field

This invention relates generally to an apparatus for collecting biological specimens. More particularly, the invention relates to an apparatus for the collection and transportation of stool specimens.

Background Of The Invention

5        Stool specimens are used with increasing frequency for the screening and diagnosis of disease. Evidence of parasitic, infectious, or inherited disease may be found in stool. For example, the presence of carcinoembryonic antigen or blood in stool is indicative of colorectal cancer. Stool-based assays for parasitic organisms are also widely available.

10        A significant problem with using stool specimens in screening or diagnosis arises in the collection of the specimen. Depending on its physical state, the specimen may be difficult to collect into a container. Moreover, the handling of a specimen raises sanitary concerns. Merely obtaining a specimen may increase the risk of disease transmission, especially if sanitary procedures are not followed. This is especially true if the patient is responsible for obtaining the specimen. The odor often associated with a stool specimen, and the frequent need to transport  
15        the specimen also contribute to the problems associated with sample collection.

      Attempts have been made to solve these problems. For example, Aslam, U.S. Patent No. 4,101,279, reports a disposable bowl adapted to fit onto a toilet for collection of stool. Such a device eliminates the need for the patient to handle the specimen directly. However, the patient (or technician) is still exposed to the sample, resulting in possible contamination and the  
20        presence of odor. Moreover, the Aslam device contains blades for homogenization that may present a danger to the patient.

      Paulin, U.S. Patent No. 4,309,782, also reports a bag adapted to fit onto a toilet for collection of stool. The device reported by Paulin also provides for scraping excess stool out of the bag after use.

25        While these and other devices of the art have attempted to solve the problems associated with collection of stool, none have provided a solution that minimizes handling of the specimen,

- 2 -

minimizes odor and contamination, and provides for easy transport of the specimen. Accordingly, there remains a need in the art for a device for safe and secure collection of stool.

#### Summary of the Invention

The present invention provides an apparatus for a collecting, storing, and/or shipping a stool specimen. Generally, the invention provides a housing having attached thereto a retractable bag for collecting the specimen. The bag is retracted by a draw string or chord (e.g., a lanyard) attached thereto, or preferably by a slider attached to the housing and to which the draw string is attached for moving the slider. In use, the patient places a device of the invention on a toilet, deposits stool into the bag, and pulls the draw string thereby to engage the slider to retract the bag. The patient may then urinate or further defecate. In a preferred embodiment, the bag is retracted into a portion of the housing. An advantage of a device of the invention is that the bag can be closed by the patient while the patient is still seated on the device.

Also in a preferred embodiment, the housing is shaped to fit onto a toilet seat. A preferred housing releasably attaches to the toilet seat or may comprise a non-slip surface for contacting the toilet. The housing may comprise padding to increase patient comfort. A preferred housing is preferably constructed of cardboard or plastic but may be constructed of any useful material. The housing may comprise supports for resting the apparatus on a toilet seat. The supports may be folded over the housing for compact transportation of the apparatus.

A stool specimen collector of the invention comprises a bag for collection, storage, and/or transport of the specimen. Preferably, a bag for use in an apparatus of the invention is releasably attached to the housing, preferably on the underside of the housing. In a preferred embodiment, the bag may be movably attached in a groove in the housing in order to facilitate closure of the bag. However, the bag may be fixedly attached to the housing at the convenience of the manufacturer or the technician. The bag is constructed of any suitable material such as polyethylene or PVC, and is preferably opaque. In a preferred embodiment, the bag may contain a buffer, or other additives to retard degradation of the specimen, and to optionally reduce odor.

A preferred apparatus comprises a slider attached to a draw string for closing the bag. In a preferred embodiment, the bag comprises a spring beam holding the bag in an open position. The spring beam deforms to a closed position under the housing when the bag is closed. The slider is preferably engaged on the underside of the housing, such that when the draw string is pulled the slider sweeps the underside of the housing, thereby gathering the perimeter of the bag and causing the bag to close. In an alternative embodiment, the draw string itself is attached to

- 3 -

the bag for closure and no separate slider is used. Thus, the draw string may be any material or configuration that is capable of closing the bag. It is not necessary for the draw string to remain attached to the bag after closure. Thus, the draw string may be detachable. A preferred draw string is constructed of nylon, and may be a loop, straight chord, braided, or any other configuration capable of closing the bag. Preferred bag closure mechanisms include a flexible tongue and groove assembly, a zipper, a thermal seal, an adhesive, a "zip-lock" assembly and others known in the art to effect closure of the open perimeter of a collection bag.

Also in a preferred embodiment, instructions for using the apparatus are attached to or printed on the housing.

Another embodiment of the invention provides methods for obtaining a stool specimen. In one embodiment, methods comprise placing a stool collector apparatus over a toilet, sitting over or on the apparatus, evacuating a stool into the collection bag, pulling the draw string to close the collection bag, and retracting the collection bag under the housing or bracket. A particular advantage of this embodiment is the collection bag is closed while the patient is still seated.

Additional aspects and advantages of the invention are apparent upon consideration of the following detailed description thereof.

#### Brief Description of the Drawings

In the drawings, like reference characters generally refer to the same part throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention.

FIG. 1A is a bottom view of the stool specimen collector apparatus.

FIG. 1B is a front view of the stool specimen collector apparatus.

FIG. 2 is a side view of the collection bag.

FIG. 3 is a schematic diagram illustrating the method of using the stool specimen collection apparatus.

#### Detailed Description of the Invention

Referring to FIGS. 1A and 1B, shown is a bottom view (1A) and a side view (1B) of a preferred stool specimen collector apparatus 10. The stool specimen collector apparatus 10 comprises a housing 12 which comprises a center U-shaped support 14 which is connected to two side supports 16 and 18. The side supports 16 and 18 are hinged to center support 14 in such a way as to support the stool specimen collector apparatus 10 when it is placed on a toilet (not

- 4 -

shown), and to allow the side supports 16 and 18 to be folded under the center support 14 when the stool specimen collector apparatus 10 is not being used.

At least a portion of a collection bag 20 is attached to the center support 14. Preferably, the collection bag 20 is removably attached to the center support 14. In FIG. 1A, the rear portion of the collection bag 20 is attached by rivets 22 through holes 21 in the collection bag 20 into the center support 14 (see also FIG. 2). Alternatively, attachment of the collection bag 20 is accomplished by other known methods, such as heat staking. FIG. 2 is a side view of the collection bag 20.

As shown in FIGS. 1A and 1B, the front of the collection bag 20 also includes a spring beam 24 which is preferably an integral part of the collection bag 20. The spring beam 24 is a narrow strip of resiliently biased material but has sufficient vertical height to prevent vertical deflection of the collection bag 20 away from the center support 14. The spring beam 24 is initially flexed outward toward the front of the toilet bowl when the apparatus is in use, and provides support for the collection bag 20 in the open position.

A preferred collection bag 20 comprises a thin flexible plastic film or any other material known to those skilled in the art for containing a biological sample. The collection bag 20 may be opaque to prevent the individual from viewing the contents, or the collection bag 20 may be clear to allow visual analysis by technicians.

As shown in FIG. 2, the top edges of the collection bag 20 preferably have a zipper 26, in which the front portion of the collection bag 20 contains a first portion of the zipper 26A, and the back portion of the collection bag 20, which is attached to center support 14, contains a second portion of the zipper 26B. In one embodiment the zipper 26 runs the entire length of the open perimeter of the collection bag 20. A preferred zipper is an ITW Maxgrip UX202T. The collection bag 20 may have alternative closures, such as an adhesive closure, or others known in the art.

Mounted to the underside of the center support 14 is a slider 28 that runs along slider track 30. The slider 28 is attached to the zipper 26 of collection bag 20. The slider 28 is attached to a draw string 32. The draw string 32 extends from the slider 28, around the center support 14, under side support 16, and extends through an opening 34 in side support 16. A handle 36 is attached to the end of the draw string 32 as shown in FIG. 1A.

A method for using a stool specimen collector apparatus 10 is illustrated in FIG 3. An individual places the stool specimen collector apparatus 10 on a toilet 8. The user then sits on or

- 5 -

over the stool specimen collector apparatus 10 and evacuates a stool sample 6 into collection bag 20. The user then pulls draw string 32 via handle 36 which closes the collection bag 20 by pulling the slider 28 which zips zipper 26 closed. As the collection bag 20 is being closed, the spring beam 24 at the front of collection bag 20 begins to deflect backwards in response to the zipper 26 closure which moves the closing collection bag 20 under center support 14.

In addition, the stool specimen collector apparatus device 10 may have a drape 36 which covers the front of the collection bag 20. The drape 36 has an opening 38 in the top of the drape 36 to allow stool to pass into collection bag 20. After a stool has been evacuated into the collection bag 20, and as the collection bag 20 is being closed, the drape 36 falls in to cover the collection bag 20 to protect the collection bag 20 during the rest of the toileting process. After toileting, the drape 36 can be detached and disposed.

A shipping container (not shown) may be used to ship the stool specimen collector apparatus, both prior to use, and after use toward a laboratory for analysis. The shipping container may contain one or more over-bags (not shown) to contain the used stool specimen collector apparatus 10 prior to placing the stool specimen collector apparatus 10 into the shipping container. Alternatively, the side supports 16 and 18 may fold over the housing 12 in order to form a shipping container.

It is envisioned that components of the stool specimen collector apparatus are reusable. In one embodiment the support bracket 12, slider 28 and draw string 32 are reusable.

Other aspects and advantages of the invention are apparent upon consideration of the disclosure herein.

- 6 -

Claims

What is claimed is:

- 1 1. An apparatus for collecting a stool specimen, the apparatus comprising:  
2 a housing;  
3 a collection bag attached to said housing; and,  
4 a draw string attached to said bag for use in closing said bag.
- 1 2. An apparatus for collecting a stool specimen, the apparatus comprising:  
2 a housing;  
3 a collection bag attached to said housing;  
4 a slider movably attached to said housing and capable of engagement with said collection  
5 bag; and,  
6 a draw string attached to said slider.
- 1 3. The apparatus of claim 1, further comprising a center support.
- 1 4. The apparatus of claim 3 wherein said apparatus further comprises two side supports  
2 foldably attached to said center support, thereby to enable said side supports to fold under said  
3 housing when said apparatus is not in use.
- 1 5. The apparatus of claim 4 wherein said housing is shaped to conform to a standard toilet  
2 seat.
- 1 6. The apparatus of claim 1 wherein said housing has instruction printed thereon or enclosed  
2 therewith.
- 1 7. The apparatus of claim 1 wherein said collection bag is opaque.
- 1 8. The apparatus of claim 1 wherein said collection bag is closeable.
- 1 9. The apparatus of claim 1 wherein said collection bag further comprises a spring beam.
- 1 10. The apparatus of claim 9 wherein said collection bag is retractable under said housing.
- 1 11. The apparatus of claim 10 wherein said collection bag comprises a zipper.
- 1 12. The apparatus of claim 10 wherein said collection bag comprises an adhesive.
- 1 13. The apparatus of claim 1 wherein said collection bag is removable from said housing.
- 1 14. The apparatus of claim 2 wherein said slider is slideable along an opening of said  
2 collection bag.
- 1 15. The apparatus of claim 1 wherein said draw string comprises a handle.
- 1 16. The apparatus of claim 1 further comprising a drape, wherein said drape is attached to  
2 said housing.



- 7 -

- 1 17. The apparatus of claim 16 wherein said drape is removable.
- 1 18. The apparatus of claim 2 wherein said housing, said slider and said draw string are  
2 reusable.
- 1 19. A method of obtaining a stool sample comprising:  
2 evacuating a stool into said collection bag; and,  
3 pulling said draw string to close said collection bag and retracting said collection bag  
4 under said housing.



2/3

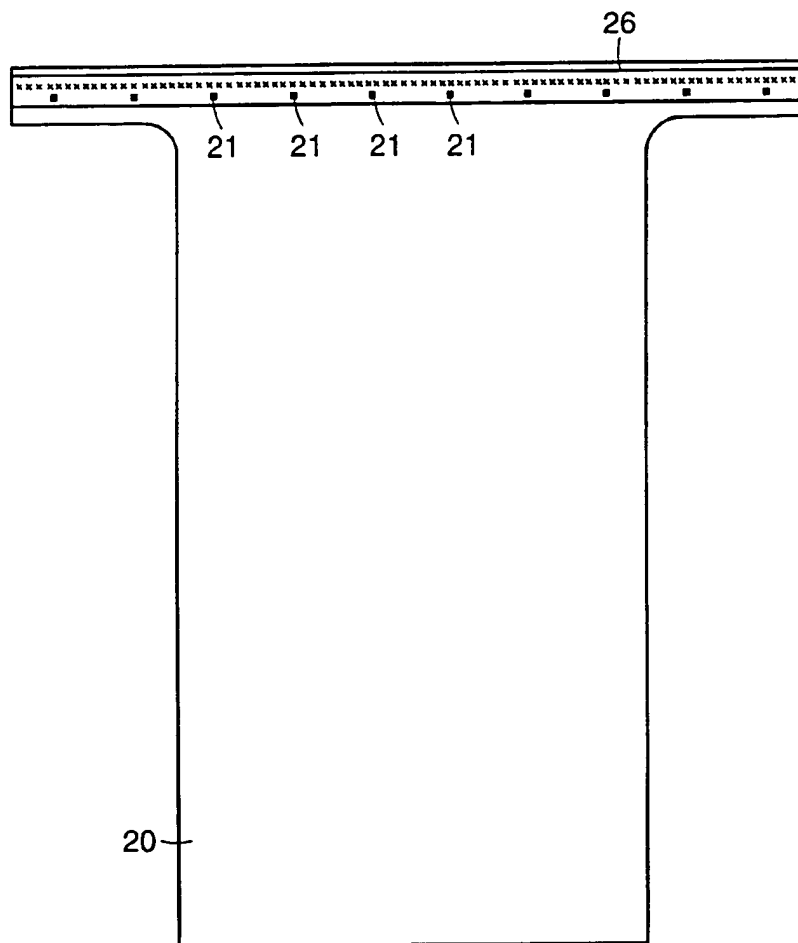


FIG. 2

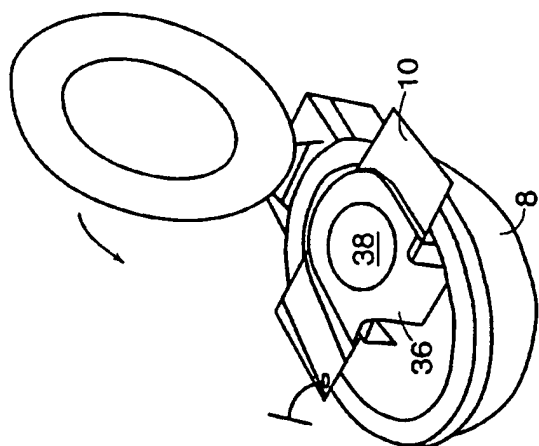


FIG. 3-1

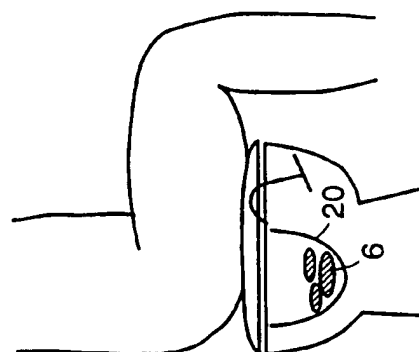


FIG. 3-2

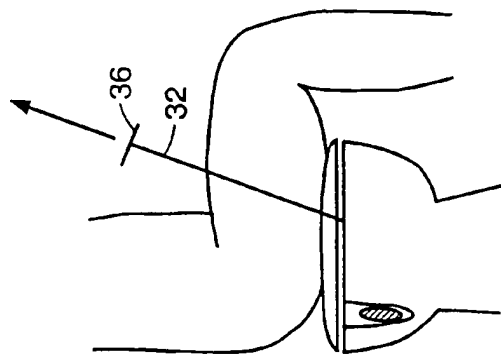


FIG. 3-3



FIG. 3-4

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 00/11297

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61B10/00 A47K11/10

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61B A47K A01K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 720 919 A (OURY) 15 December 1995 (1995-12-15) page 4, line 9 - page 5, line 19; figures 1-4	1,3-5,7, 13,19
Y		6,15
A		2
X	GB 2 196 246 A (VANN BRENTON) 27 April 1988 (1988-04-27) page 1, line 42 - line 65; figures 1-3	1,7,8, 13,19
A		2
X	US 408 607 A (REES) 10 April 1934 (1934-04-10) page 2, line 52 - line 125; figures 1,2	1,19
	--- -/-- ---	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

13 July 2000

Date of mailing of the international search report

11/08/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Ducureau, F

# INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 00/11297

## C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 309 782 A (PAULIN ESTEBAN) 12 January 1982 (1982-01-12) column 2, line 25 - line 27; figures 1,3	6
A	---	1,2,19
X	GB 2 229 699 A (HARRISON IAN ALEXANDER) 3 October 1990 (1990-10-03) page 8, paragraph 3; figures 1-4	1-5,7,8, 19
A	---	2
Y	US 4 872 420 A (SHEPARD DANIEL R) 10 October 1989 (1989-10-10) abstract; figure 5	15
A	---	1-5,8,19
	FR 2 740 672 A (LE FOURN GILBERT) 9 May 1997 (1997-05-09) abstract; figures 1,5 -----	

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 00/11297

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2720919 A	15-12-1995	FR 2720918 A	15-12-1995
GB 2196246 A	27-04-1988	NONE	
US 408607 A		NONE	
US 4309782 A	12-01-1982	NONE	
GB 2229699 A	03-10-1990	WO 9011714 A	18-10-1990
US 4872420 A	10-10-1989	NONE	
FR 2740672 A	09-05-1997	AU 7576196 A	29-05-1997
		EP 0865254 A	23-09-1998
		WO 9717019 A	15-05-1997